Both groups were similar at baseline. Drop out was 28.8%. Intention to treat analysis. Adherence increased significantly in IG (p=0.046), NNT=6.37 (CI95%,3.25-142.8). Factors related to adherence: intervention (OR=1.88, CI95%,1.01-3.52), number of exacerbation (OR=0.66,CI95%,0.48-0.91), number of visits to health centre (OR=0.93,CI95%,0.87-1.00), severity (OR=0.677,CI95%,0.43-1.04), number of devices (OR=2.4,CI95%,1.09-5.30), SGRQ-Activity scale (OR=0.978,CI95%,0.95-1.00), SGRQ-Impact scale (OR=1.03,CI95%,1.00-1.06), inhaled-beta2-adrenérgic (OR=0.16, CI95%,0.059-0.43), xanthine (OR=0.199, CI95%,0.05-0.77). Rho coefficient=$6.07x10^{-6}$ (p=0.498). **CONCLUSIONS:** The more adherent patient was that who showed a lower number of visits to health centre, exacerbations, number of devices, level of severity, and impact on daily activities but with higher disease impact. The beta-2-adrenergic and xanthine treatment are associated with no adherence.

PRS45

HOW DO PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) USE THEIR INHALERS? COMMON MISTAKES. TECEPOC STUDY

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OBJECTIVES: To test the inhaler use in COPD patients. Frequent mistakes. **METHODS:** Design: Cross-sectional study at the beginning of a Multicenter patients' preference trial (ISRCTN15106246) Patients: 465 COPD patients from 9 health care centres, with inhaled treatment, written consent. Non-probabilistic consecutive sampling. Variables: inhaler devices, performance of correct inhalation technique, type of mistakes. Age, sex, Inhalatory pick flow, COPD severity stage, prescribed medication. Basal dyspnea index (BDI). Statistical analysis: Mean, frequency. 95% confidence interval. **RESULTS:** Predominance of males (91.4%), mean age 69.8 years (CI95%,69.00-70.59); FEV1(mean)=55.91%(IC95:53.62-58.2), mixed respiratory pattern (65.9%). Severity stage: 15.7% mild, 44.1% Moderate, 40.3% Severe. Pharmacological treatment: inhaled-beta2-adrenergic (88.8%); inhaled-corticosteroids (76.7%); inhaled-anticholinergic (70.7%); mucolitycs (19.4%); xanthine (7.3%); oral-corticosteroids (1.3%). BDI: grade 2. Inhalation technique: 84.9% had received instruction about inhalation techniques (48.6% from neumologist, 42.1% from general practitioner). The instruction was an explanation without device (59.6%). 67.3% of patients used Handihaler, 54.8% Accuhaler, 31.8% Turbuhaler, 26.9% pressurised metered dose inhaler (pMDI). The 91.3% of patients performed an incorrect inhalation technique with handihaler, 89.5% with Turbuhaler, 85.6% with Accuhaler and 91.7% with pMDI. The most common mistakes in all devices were related to the action consist on: emptying or almost emptying the lungs before activating the spray (79.8%) and holding breath for at least 8-10 seconds or for as long as possible when inhalation is complete (69.5%). The most common mistakes per device were related to: repeating the inhalation with Handihaler (10%), Loading the dispenser correctly in Accuhaler (8.2%) or Turbuhaler (16.6%) and hand-breath coordination in pMDI (52.8%). **CONCLUSIONS:** A high percentage of patients with COPD performed an incorrect inhalation technique although they had been received instruction about this. The most common mistakes are more related to the patient's attitude than to the type of device.

PRS46

TECEPOC STUDY. HOW TO IMPROVE THE INHALATION TECHNIQUES IN PATIENT WITH COPD. THE INFLUENCE OF PREFERENCES

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OBJECTIVES: to test the efficacy of two educational interventions to improve the inhalation techniques in patients with COPD and the influence of patient' preference. **METHODS:** Design: Multicenter patients' preference trial or comprehensive cohort design ISRCTN15106246. Patients: 465 COPD patients (to detect a difference between groups of 25%, 80% statistical power, 95% confidence level, 40% expected losses), with inhaled treatment, written consent. Non-probabilistic consecutive sampling. Allocation: Patients without strong preferences for a treatment are randomised: RCT group (block randomization), and those with strong preferences are given their choice: PPS group. Variables: Primary outcomes: Performance of correct inhalation technique. Secondary outcomes: Pick flow, dyspnea (Baseline dyspnea index), Functional status (forced spirometry). Interventions: Intervention-A: Written information. A leaflet with the correct inhalation technique for the main inhaler devices used in our area. *Intervention-B:* Intervention-A + individual training (by instructors). Follow-up: 3 month, visits: baseline, 1 month, 3 month. Statiscal analysis: Mean, frequency, 95% confidence interval at baseline. Number Needed to Treat for a benefit (NNT) was calculated. Intention to treat analysis. **RESULTS:** Predominance of males (91.4%), mean age 69.8 years (CI95%, 69.00-70.59); FEV1(mean)=55.91% (IC95%, 53.62-58.2), mixed respiratory pattern (65.9%). Severity stage: 15.7% mild, 44.1% Moderate, 40.3% Severe. Pharmacological treatment: inhaled-beta2-adrenergic (88.8%); inhaled-corticosteroids (76.7%); inhaled-anticholinergic (70.7%); mucolitycs (19.4%); xanthine (7.3%); oral-corticosteroids (1.3%). BDI: grade 2. Primary outcome: better inhalation technique (p=0.002) in the PPS group, NNT=7.4 (IC95%, 4.52-20). Among the RCT cohorts: there was no difference between control and intervention A and there were statistically significative differences between intervention B versus control (p<0.0001), NNT=2.44 (IC95%, 1.87-3.5) and versus intervention A, NNT=2.85 (IC95%, 2.08-4.56). In the PPS cohorts: there was a difference (p<0.0001) between intervention B versus intervention A, NNT=2.33 (IC95%, 1.5-3.2). **CONCLUSIONS:** The performance of a correct inhalation Technique improves with monitor training. The patients' preferences enhance the efficacy of intervention.

PRS47

RELATIONSHIP BETWEEN MEDICATION ADHERENCE AND QUALITY OF LIFE IN COPD – SYSTEMATIC REVIEW

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OBJECTIVES: Adherence and health-related quality of life (HRQoL) are two important indicators in determining success of drug treatments. Although medication adherence and HRQoL have been studied intensively, less is known about the association of these factors. This research aims to undertake a systematic review of the published literature on the relationship of medication adherence and HRQoL in patients with chronic obstructive pulmonary disease (COPD). No comprehensive review has been published in this topic so far. **METHODS:** Peer-reviewed English-language articles that examined the relationship between adherence/compliance/persistence to medication and HRQoL in COPD were identified through database (Medline, EMBASE) searches. Reports until April 2013 were screened. Papers related to oxygen therapy were excluded. **RESULTS:** Of the 243 papers reviewed, eight studies met the inclusion criteria and were analyzed in our systematic review. Evidence suggests that relationship between medication adherence and HRQoL is dual. Non-adherence does not have a clear negative impact on HRQoL. Adherence to medication may affect HRQoL due to more factors, such as effectiveness/efficacy and side effects of the medication, daily life limitation and social stigmatization caused by the therapy. Effect of non-adherence on HRQoL can be derived from the resultant of these factors. Nevertheless, HRQoL may also influence patients' drug use; poor or good HRQoL may trigger non-adherence. Relationship between adherence and HRQoL may differ depend on the duration of the previous therapy (as therapy in newly diagnosed COPD patients may improve HRQoL more than in patients treated previously for longer durations) and on the study design (cross-sectional versus longitudinal follow-up study) as well. **CONCLUSIONS:** Association of medication adherence and HRQoL is multiple. Results from previous studies are limited. Further scientific evaluations are needed to better understand the dynamics between these factors. Such information would be critically important and needs to be considered when integrating adherence into health-economic evaluations.

PRS48

ESTIMATION OF GENERIC UTILITIES IN SPANISH CHRONIC OBSTRUCTIVE PULMONARY DISEASE PATIENTS

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OBJECTIVES: Chronic obstructive pulmonary disease (COPD) is a major public health problem and one of the leading causes of chronic morbidity and mortality worldwide. This study aims at determining generic utilities for Spanish COPD patients stratified by international guidelines GOLD 2006 (airflow limitation) and GOLD 2013 (airflow limitation, exacerbation history and symptoms), and Spanish guidelines GesEPOC (clinical phenotypes). **METHODS:** Multicentre, observational, cross-sectional study, carried out in 15 Pulmonology Spanish public services, including patients aged 40+, diagnosed with COPD, who have not experienced an exacerbation in the previous 2 months and receiving pharmacological treatment for COPD. Utilities were derived from EQ-5D-3L scores. Medians, means and standard deviations (SD) were computed for groups of patients based on GOLD 2006, GOLD 2013 and GesEPOC classifications. Differences in median utilities between groups were assessed by means of Kruskal-Wallis tests. Post-hoc pair-wise comparisons were based on Wilcoxon tests (Bonferroni-adjusted). **RESULTS:** A total of 346 patients were included in the analysis. Statistically significant median differences in utilities by groups of patients were found. GOLD 2006: moderate (n=135, median=0.87, mean=0.81, SD=0.22); severe (n=145, median=0.80, mean=0.71, SD=0.29); very severe (n=66, median=0.67, mean=0.57, SD=0.35); (p<0.001). All pair-wise comparisons were statistically significant (p<0.001). GOLD 2013: group A (n=28, median=0.98, mean=0.94, SD=0.06); group B (n=66, median=0.87, mean=0.80, SD=0.22); group C (n=30, median=0.98, mean=0.87, SD=0.24); group D (n=222, median=0.74, mean=0.66, SD=0.30); (p<0.001). All pair-wise comparisons were statistically significant (p<0.002), excepting groups A and C comparison. GesEPOC: (A) non-exacerbator (n=215, median=0.84, mean=0.78, SD=0.23); (B) overlap COPD-asthma (n=21, median=0.80, mean=0.80, SD=0.19); (C) exacerbator with emphysema (n=46, median=0.74, mean=0.59, SD=0.40); (D) exacerbator with chronic bronchitis (n=64, median=0.74, mean=0.62, SD=0.33); (p<0.001). Pair-wise comparisons between phenotypes A and C (p<0.002) and phenotypes A and D (p<0.001) were statistically significant. **CONCLUSIONS:** Generic utilities are associated with airflow limitation, exacerbation history, symptoms and clinical phenotypes in a sample of Spanish COPD patients.

PRS49

PATIENT-REPORTED OUTCOME (PRO) CLAIMS IN PRODUCTS APPROVED FOR CHRONIC OBSTRUCTIVE PULMONARY DISEASES (COPD) IN EUROPE AND THE UNITED STATES

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OBJECTIVES: 1) To identify COPD products approved with a Patient-Reported Outcome (PRO) labeling claim in Europe and the USA, and 2) to list the differences found in Europe vs. the USA in terms of products and labeling. **METHODS:** The search was performed on the FDA- and EMA-approved medicinal product labels and medical reviews/scientific discussions (from January 1995 - February 2013 inclusive). **RESULTS:** A total of 25 COPD products were retrieved: 11 were approved by the EMA and 14 by the FDA. Only three INN were approved by both agencies (aclidinium bromide, indacaterol, and roflumilast), representing 11 products (EMA, n=8; FDA, n=3). Out of the 25 products approved, 15 have a PRO claim (EMA, n=8; FDA, n=7). When focusing on the INN approved by both agencies, the review showed that the FDA and the EMA agreed on the granting of a PRO claim (i.e., "yes" for aclidinium bromide and indacaterol, and "no" for roflumilast). The FDA and the EMA reviewed the same clinical studies. However, the labeling text differs between the agencies. The FDA label of aclidinium bromide does not provide any mention of results measured by the St. George's Respiratory Questionnaire (SGRQ) and the Transition Dyspnoea Index (TDI), while the EMA label does. As for indacaterol, the FDA label does not mention any TDI results, while the EMA label does. Reasons for these discrepancies are found in the FDA medical reviews. The TDI has been assessed as inadequate for use as a CT endpoint. As for the SGRQ, the results met the threshold of clinically meaningful improvement in only